DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

RECEIVED
JAN 18 1996
DEC 22 1995 OFFICE OF PETITIONS

Re: ADENOSCAN®
Docket No. 95E-0303

Received #37 from Comm. Off. 12/28/95

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,070,877, filed by Medco Research, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ADENOSCAN®, the human drug product claimed by the patent.

The total length of the regulatory review period for ADENOSCAN® is 2,688 days. Of this time, 768 days occurred during the testing phase and 1,920 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 9, 1988.

   The applicant claims December 10, 1987, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 9, 1988, which was thirty days after FDA receipt of the IND on December 10, 1987.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 14, 1990.

   The applicant claims February 9, 1990, as the date the New Drug Application (NDA) for ADENOSCAN® (NDA 20-059) was initially submitted. However, while FDA records indicate that the applicant submitted NDA 20-059 on February 9, 1990, the FDA received the NDA on February 14, 1990, which is considered to be the NDA initially submitted date.

3. The date the application was approved: May 18, 1995.

   FDA has verified the applicant's claim that NDA 20-059 was approved on May 18, 1995.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Jae H. Kim
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